



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,761	04/03/2001	Yasushi Watanabe	2500.7	4768

5514 7590 05/21/2003

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

SPEAR, JAMES M

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 05/21/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/806,761	Applicant(s) WATANABE, ET AL
Examiner JAMES M. SPEAR	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Feb 7, 2003

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 and 10-14 is/are rejected.

7) Claim(s) 9 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

Art Unit: 1615

Applicants' Petition for Extension of time and Amendment filed February 7, 2003 has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and fail to further define the subject matter in a clear concise manner since they recite limitations directed to a method, while claim 1 is a tablet composition.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 9104621. The claim remains rejected for the reasons set forth in Paper No. 4, mailed, July 30, 2002.

Applicant's arguments filed February 07, 2003 have been fully considered but they are not persuasive. Applicants feel the JP-621 reference does not disclose a

Art Unit: 1615

pressed composition containing an active substance which is affected by the lubricant which is later applied. A tablet having an active ingredient which may discolor or lower its potency when directly contacting the lubricating jelly. The reference shows drugs classified in International class A61K 9/28, which encompasses coated pills or tablets. The reference does not have to recite the adverse activity of lubricant to active, which is considered an inherent property to meet applicants' limitations. Applicants' claim is not limited to any lubricant. Applicants show a lubricant coated substrate, as does the reference.

Claims 1-4, 7, 8, and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Leal et al. The claims are rejected for the reasons set forth in Paper No. 4.

It is the position of this office that Leal does inherently teach lubricants which adversely affect the ascorbic acid or other active agents. The Leal et al tablets comprise the same lubricants and active agent as applicants'. Column 5, lines 4-11. The reference need not recite the adverse feature to meet the limitations of applicants' claims. The lubricants are identical and therefore have the same properties as applicants'.

Art Unit: 1615

Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah US 4,047,866. While applicants feel the Shah reference fails to disclose that the lubricant is applied using pulsating vibration air, the reference shows a process wherein the identical lubricants as applicants use are sprayed onto the punch faces and dies, which are the same surfaces disclosed by applicants. Using pulsating vibration air is not considered a patentable distinction over the Shah reference. See column 2, lines 43-68.

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-8 and 10-14 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1615

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

James M. Spear

May 17, 2003

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
ART UNIT 1615